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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,738	05/24/2000	MICHAEL BLATT	2186PB-1	2749

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,738

Applicant(s)

BLATT ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 27-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election without traverse of Invention 1, Claims 1-20 and 26 in Paper No. 11, filed July 16, 2001 is acknowledged. Claims 21-25, and 27-56 have been withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions.

Priority is set to September 30, 1997.

OK The disclosure is objected to because of the following informalities: throughout the specification and claims, sequence identification numbers should follow the format provided in 37 CFR 1.821, that is -- SEQ ID NO: 1 --, for example.

The priority applications, including foreign priority applications, have not been cross-referenced at page 1.

Appropriate correction is required.

OK The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 3, para. 6, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

OK Claim 3 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

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to object to the other as being a substantial duplicate of the allowed claim. See MPEP

§ 706.03(k).

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18, 20, and 26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed proteins are not stated to be isolated or purified or in any way touched by the hand of man. Therefore, these claims are considered to be products of nature and therefore directed to non-statutory subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 13-17, 18, 20, and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins capable of affecting ABA response and comprising the hydrophobic C-terminal, coiled coil region, EF-and consensus sequence, nucleotide binding site, hydrophobic N-terminal of SEQ ID NO: 2, the Abl1 gene product having calcium-modulated protein phosphatase comprising an EF hand consensus sequence, and the DS2 protein having a hydrophilic N-terminal, a coiled-coil region, and a hydrophobic C-terminal, does not reasonably provide enablement for all proteins comprising a hydrophobic C-terminal, coiled coil region, EF-and consensus sequence, nucleotide binding site, hydrophobic N-terminal and affecting ABA response, and variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the invention commensurate in scope with these claims. In *Ex parte Forman* (230 USPQ 546) the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation:

1) Quantity of experimentation necessary: The specification at page 1 teaches that abscisic acid (ABA) is a plant phytohormone which plays a role in the growth and development of plants. It is also a stress-induced hormone that protects plants from adverse environmental conditions. Its actions are on long term physiological changes that involve modulation of gene expression at the transcriptional level. Over 150 genes have been shown to be responsive to ABA. Therefore, proteins affecting the ABA response, that is, carrying out or manifesting the ABA signal are far flung, depending on the modulation of genes. The gene transcriptions which are modulated by ABA are not described in the specification and therefore the multitudes of encoded proteins that would be considered to affect ABA signaling are not disclosed. Whether the gene transcription is augmented or attenuated by ABA is not disclosed. Therefore, protein levels can be increased or decreased and be a protein that manifests the ABA response. The function of the proteins are not set forth in the specification, and therefore the identification of a protein via its function in growth and development or during stress and its function in the ABA response is not disclosed. In total, the quantity of experimentation necessary to determine proteins that carry out the ABA "global-like" response, and having any one of a hydrophobic C-terminal, coiled coil region, EF-and consensus sequence, nucleotide binding site, or hydrophobic N-terminal, including any variants of proteins that carry out the ABA "global-like" response, and having any one of a hydrophobic C-terminal, coiled coil region, EF-and consensus sequence, nucleotide binding site, or hydrophobic N-terminal would require undue experimentation for one having ordinary skill in the art.

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2) Amount of direction or guidance presented: Direction and guidance is provided in an overall sense – see the strategy set forth on page 19+. However, the strategy is oocyte expression of RNA, which is random.

3) Presence or absence of working examples: There are working examples, which the protein having SEQ ID NO: 2 is found to be responsive to ABA.

4) Nature of the invention; 5) State of the prior art; 6) Relative skill of those in the art: The nature of the invention is complex and the prior art recognizes proteins that are responsive to ABA. Those working in the art are highly skilled.

7) Predictability or unpredictability of the art: It is not predictable which proteins will be involved in ABA signaling, including those proteins have augmented levels in response to ABA.

8) Breadth of the claims: Given that there are at least 150 known genes that are modulated by the ABA signal, and the ABA is known for its global-like effect on growth and development as well as environmental stress, and therefore affecting multitudes of proteins that participated in growth and development as well as environmental stress, the breadth of the claims are beyond reasonable scope for the identification of a protein having SEQ ID NO: 2.

For all of these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

Claims 1- 20 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims lack written description in the specification because there is no correlation of structure and function. For example, what is the function of a protein having a hydrophobic C-terminal? or comprising amino acids 114-119 of SEQ ID NO: 2? Applicants may wish to provide a functional language in their claims so that one

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skilled in the art can identify the claimed proteins. Regarding Claim 17, the specification does not teach a mammalian protein responsive to ABA. Regarding Claims 19 and 20, the specification does not provide any protein which binds to SEQ ID NO: 2, for example, and therefore these claims lack written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 19, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 refers to a protein comprising the amino acid sequence depicted in SEQ ID NO: 3. However, SEQ ID NO: 3 is a nucleotide sequence. Claim 19 does not set forth any steps in which to practice the method. Claim 26 depends from a non-elected claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17, 20, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Leung et al. (1994; Science 264:1448-1452). Leung et al. teach *Arabidopsis* ABA response gene product ABI1, which is a calcium-modulated protein phosphatase. This phosphatase comprises an EF hand consensus sequence as shown in Fig. 4. Therefore, Leung et al. teach a protein capable of

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affecting ABA response and having an EF hand consensus sequence (Claim 1, 26) from plants (Claim 17). Leung et al. also teach that Abl1 may interact with p34^{cdc2} (page 1450, col. 2, para. 2). Thus, p34^{cdc2} anticipates Claim 20.

Claims 1, 17, 20, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Silhavy et al. (1995; Plant Molecular Biology 27:587-595). Silhavy et al. teach a stress gene product DS2 from *S. chacoense*. The DS2 protein has a hydrophilic N-terminal region, a coiled coil region, and a hydrophobic C-terminal and is weakly responsive to ABA (page 593, mid-col. 2; Claims 1, 26) from plants (Claim 17).

No Claims are Allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

November 18, 2002

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

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